

REMARKS

I. Status of the Claims

Claims 1 and 11 are amended to recite that the microcrystalline cellulose has an average particle diameter of 2-10 micrometers. Support for this amendment can be found in the Specification as filed, e.g., at page 6, paragraph [0015], lines 1-5. The Applicants submit that this amendment does not raise any new issues of patentability and is being made to put the claims in better form for appeal, as permitted under 37 C.F.R. § 1.116(b)(2). Claims 5 and 6 were cancelled by previous amendment without prejudice to or disclaimer of the subject matter therein. Claims 3, 4, and 18 are currently withdrawn from consideration.

These amendments do not introduce new matter, and their entry is respectfully requested. Upon entry of the foregoing amendment, claims 1-4 and 7-19 are pending to be examined on their merits, with claims 1 and 11 being the independent claims. Reconsideration of this application is also respectfully requested.

II. Claim Rejection – 35 U.S.C. § 103

Claims 1, 2, 7-17, and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 95/34275 in view of JP 0558861. (Office Action, at page 2, lines 7-8.) The Applicants respectfully traverse this rejection.

Specifically, the Office indicates that it does not believe that the data presented in the Nakao Declaration show unexpected results in light of JP 055861, which the Office believes already acknowledges that smaller particle size increases shape-holding ability, so that particle sizes of < 10 microns are expected to show enhanced smoothness, shape holding ability, and dispersibility. (Office Action, at page 2, line 16, to page 3, line 2.) Moreover, in response to the Applicants' argument that powdered and microcrystalline types of particulate cellulose have entirely different physical properties, the Office states that this argument is not persuasive because WO 95/34275 (the primary reference) "clearly gives the skilled artisan the option to choose the microcrystalline type over the powdered type if he or she so desires." (Office Action, at page 3, lines 3-8.) Lastly, in response to the Applicants' argument that WO 95/34275 teaches

away from the claimed invention, the Examiner states that “a reference is good for all of its teachings - not just those embodiments that are preferred by an inventor.” (Office Action, at page 3, lines 9-12.)

The Applicants respectfully traverse and maintain the position that the present invention is a classic case of an unobvious selection of particular materials resulting in a combination that exhibits unexpected results. Furthermore, as emphasized in the Amendment and Response Under 37 C.F.R. § 1.111, filed on June 9, 2008, one of ordinary skill in the art would have had no reason to arrive at the presently claimed oral composition comprising the combination of microcrystalline cellulose having an average particle diameter of 2-10 micrometers with a surface active agent selected from the group consisting of alkyl glucoside and betaine based on WO 95/34275 and JP 0558861.

(i) WO 95/34275 Teaches Away

Without acquiescing to the grounds of rejection, claim 1 is amended to recite that the cellulose in the claimed oral compositions is microcrystalline cellulose having a relatively low range of average particle diameter of **2-10** micrometers.

By contrast, WO 95/34275 teaches away from the claimed composition by disclosing an oral care composition comprising a particulate cellulose cleaning/polishing agent that “may comprise the powdered and/or microcrystalline type,” but that is more suitably highly purified **powdered cellulose**. For instance, Example 6 of WO 95/34275 discloses a toothpaste composition comprising the cellulose abrasive Elcema (powdered cellulose) and cocamidopropyl betaine. The Applicants emphasize again that **microcrystalline** cellulose and **powdered** cellulose are compounds having **entirely different physical properties**. In fact, WO 95/34275 distinguishes microcrystalline cellulose from powdered cellulose. See WO 95/34275, at page 2, lines 13-25.

Additionally, WO 95/34275 discloses cellulose having a particle size of from about 1 μm to 350 μm (WO 95/34275, at page 4, second paragraph), with the most suitable range being “from

about 10 μm to about 100 μm , more suitably from about 20 μm to about 70 μm .” See WO 95/34275, at page 4, line 8. Thus, the preferred embodiments of WO 95/34275 are directed to powdered cellulose with particle size much larger than that recited in the present claims. The larger size of the particle is in contrast to the teaching of the present application. As provided in, for example, paragraph [0015] of the present Specification as filed, the presently claimed composition discloses cellulose having an average particle no larger than 10 micrometers to avoid deterioration of the composition. Thus, WO 95/34275 teaches away from the present claims.

(ii) No Reason to Combined WO 95/34275 and JP 0558861

In addition to WO 95/34275’s teaching away from the present claims, one of ordinary skill in the art would have no reason to combine the teachings of WO 95/34275 and JP 5058861.

WO 95/34275 discloses an oral hygiene composition comprising particulate cellulose, including microcrystalline-type cellulose having a size of from about 1 to 350 μm , and use of such composition in the treatment and/or prevention of dental caries and/or gingivitis. It also discloses that particulate cellulose may be used to remove stains from the teeth, to reduce and/or prevent the build-up of such stains, and is effective when used as the sole abrasive ingredient.

JP 5058861 discloses a toothpaste composition formulated with an aqueous suspension of pulverized cellulosic material having 0.3-6 μm particle size. The purpose of JP 5058861 is to provide a toothpaste composition causing no drop in viscosity despite a change in temperature or ionic concentrations, while maintaining favorable tube extrudability and shape-retaining ability.

The Office seems to consider that the present invention is obvious over WO 95/34275 in the light of JP 5058861 because WO 95/34275 discloses an oral hygiene composition comprising microcrystalline cellulose having a small overlapped range of particle diameters with that of the present invention, and JP 5058861 discloses a toothpaste composition comprising pulverized cellulosic material similar to the microcrystalline cellulose of the present invention and having *one* effect of the present invention (shape-holding ability). In other words, the Office appears to believe that obviousness follows from attending to only one effect of the present invention with

one ingredient, shape-holding ability on a tooth brush, with microcrystalline cellulose. The Applicants respectfully disagree.

A primary problem solved by the present invention is to provide excellent stability over time (inhibition of solid-liquid separation), together with holding ability and dispersibility in oral cavities (*see*, e.g., the specification as originally filed, paragraph [0011]). That is, the present invention would not have been complete if the claimed preparation were unstable over time, even if it had excellent shape-holding ability and dispersibility in an oral cavity. In fact, such stability is evaluated in the Specification as filed (*see* Table 1).

Neither WO 95/34275 nor JP 5058861 discloses or suggests this effect of stability over time with dispersibility in oral cavities for the presently claimed combination of specific surface active agents and cellulose of particular particle size.

Furthermore, Applicants note that “polyoxyethylene/polyoxypropylene block copolymer” and ethylene oxide/propylene oxide copolymers” (trade name ‘Pluronic’) are described in the cited references as non-ionic surface active agents that may be used in the disclosed preparations (*see*, e.g., page 3, paragraph [0011] of JP 5058861, and page 8, lines 23-25, of WO 95/34275). Although the descriptions of these surface active agents are not identical, they refer to identical compounds. The Applicants note that the present application has demonstrated that the stability with time effect of the present invention is not exerted with such compounds, e.g., with the compound ‘Pluronic F88’ (see Specification as filed, at Table 1, Comparative Example 4).

Since WO 95/34275 and JP 5058861 do not disclose or suggest a primary problem or effect and a specific combination of surface active agents and microcrystalline cellulose as recited in the present claims; since the present Specification demonstrates that an effect of the present invention is exerted only by such specific combination; and, furthermore, since the present Specification demonstrates that the primary effect **cannot** be exerted with the surface active agent disclosed in WO 95/34275 and JP 5058861, present claims 1, 2, 7-10 cannot be obvious over a combination of WO 95/34275 and JP 5058861.

In view of the foregoing, the Applicants respectfully submit that the present claims would not have been obvious over WO 95/34275 and/or JP 5058861, and one of ordinary skill in the art would not have a reason to combine the teachings of WO 95/34275 and JP 5058861 to reach the claimed compositions. Furthermore, even if the teachings of WO 95/34275 and JP 5058861 were combined, the presently claimed compositions would not have been arrived at.

(iii) *Present Application Discloses Unexpected Results*

Regardless of the teachings of WO 95/34275 and JP 0558861, the Applicants continue to submit that the claimed oral compositions exhibit unexpected effects from the **combination** of (1) **microcrystalline cellulose with a specific average particle diameter** and (2) a **specific surface active agent** in the composition, as evidenced by the Nakao Declaration submitted with the Applicants' June 9, 2008 reply, which indicates that a significant effect is exhibited by combining microcrystalline cellulose having an average particle diameter equal to or smaller than 10 micrometers with the surface active agents alkyl glucoside or betaine. Furthermore, as demonstrated in the Nakao Declaration, the excellent effect of the present oral composition can be exhibited only by a **combination** of microcrystalline cellulose having a specific average particle diameter equal to or smaller than 10 micrometers with these specific surface active agents.

The claimed oral composition, which does not cause solid-liquid separation during a long period of time, has excellent shape-holding ability and dispersibility in oral cavities and the like, can be obtained by combining "a specific surface active agent" and "specific microcrystalline cellulose." The specification discloses that "microcrystalline cellulose having an average particle diameter of 10 micrometers or smaller is more preferable and microcrystalline cellulose having an average particle diameter of 2-6 micrometers is most preferable" (*see* Specification as filed, paragraph [0015]).

As shown in the experimental results presented in the present Specification, the excellent stability with time is achieved by a combination of a specific surface active agent and

microcrystalline cellulose having an average particle diameter of 4 μm (see the Specification as filed, Table 1, Examples 1 and 4), and is not exerted by a combination of other surface active agents or cellulosic materials (see Comparative Examples 1-4). Moreover, it is shown that the above effects of the present invention are successfully achieved with an oral composition comprising microcrystalline cellulose having an average particle diameter of 3.7, 5.8, and with alkyl glucoside or betaine (see Examples 5, 6 and 9-13).

The data presented in the Nakao Declaration also demonstrate that (1) for shape-holding ability, a significant effect is achieved in formulations comprising microcrystalline cellulose having an average particle diameter smaller than (5 μm and 9 μm) with alkyl glucoside or betaine; and (2) for dispersibility in oral cavities, a favorable effect is achieved in formulations comprising microcrystalline cellulose having an average particle diameter smaller than 10 μm with alkyl glucoside or betaine, and that this effect increases with a decreasing average particle diameter of microcrystalline cellulose.

It can be appreciated by one of ordinary skill in the art that with respect to the relationship between shape-holding ability and dispersibility in oral cavities, higher shape-holding ability tends to decrease with dispersibility in oral cavities. However, surprisingly and unexpectedly, the Applicants found that both effects can be simultaneously achieved by combining a specific surface active agent and microcrystalline cellulose. Such a relationship is suitable for an oral composition, a distinct effect in view of conventional common technologies, and it is an effect which could not have been expected by those of ordinary skill in the art.

In addition, the Applicants note that the present invention relates to an oral composition comprising a cationic antimicrobial agent and microcrystalline cellulose having an average particle diameter of 2-10 micrometers and that this composition provides an enhanced antimicrobial effect (the antimicrobial agent resides on the tooth surface longer), thereby enhancing prevention of oral cavity diseases.

The experimental results presented in the present Specification confirm that the significantly enhanced effect is exerted by a combination of the cationic antimicrobial agent and specific microcrystalline cellulose (*see* the original specification, Table 2, Examples 14, 15, 17 and 18), and is not exerted by a combination with other cellulosic materials (see Comparative Examples 5-8). However, this effect, as well as the combination of the cationic antimicrobial agent and specific cellulose of the present invention is not disclosed or suggested either in WO 95/34275 or JP 0558861. Thus, the claims would also not have been obvious over WO 95/34275 in view of JP 0558861 to one of ordinary skill in the art.

In view of the foregoing, the Applicants respectfully submit that one of ordinary skill in the art would not have expected the properties of the oral composition as currently claimed over WO 95/34275 in view of JP 0558861. Accordingly, the claimed compositions would not have been obvious over WO 95/34275 in view of JP 0558861.

Therefore, the Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

The Applicants believe that the present application is now in condition for allowance and respectfully request favorable reconsideration.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Feb. 25, 2009

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Stephen B. Maebius
Attorney for Applicants
Registration No. 35,264